IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

TAIMAZ SARLI, Plaintiff, v. MYLAN BERTEK PHARMACEUTICALS, INC., f/k/a/ BERTEK PHARMACEUTICALS, INC., a Texas Corporation; MYLAN PHARMACEUTICALS, INC., a West Virginia Corporation; MYLAN LABORATORIES INC., a Pennsylvania corporation; CARDINAL HEALTH, INC., an Ohio Corporation; CARDINAL HEALTH FRANCE, a French Corporation; and GENPHARM, a Canadian Corporation, Defendants.	)	1:07CV43

MEMORANDUM OPINION

TILLEY, District Judge

This matter is before the Court on motion of Defendants Mylan Bertek Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., and Mylan Laboratories, Inc. (collectively "Mylan" or the "Mylan Defendants") to dismiss the Complaint for failure to state a claim [Doc. # 6]. Plaintiff Taimaz Sarli, a California resident, asserts that he suffered personal injuries as a result of taking Amnesteem, an acne medication "made, created, manufactured, assembled, designed, tested, labeled, supplied, packaged, distributed, marketed, advertised, warned, and/or sold" by the Defendants "in the State of North Carolina." [Doc. # 3, ¶ 11].

The Mylan Defendants have moved to dismiss the Complaint on the grounds that (1) Mr. Sarli's claims for strict liability are prohibited under North Carolina law; (2) Mr. Sarli's failure to warn claim is preempted by Federal Regulation; (3) Mr. Sarli's claims are barred by the applicable statutes of limitation; and (4) Mr. Sarli has failed to plead his claim for fraud with sufficient particularity. For the reasons set forth below, the Motion to Dismiss is DENIED.

I.

A motion to dismiss for failure to state a claim is intended to test the legal sufficiency of the complaint, not to decide the merits of the action. Schatz v. Rosenberg, 943 F.2d 485, 489 (4th Cir. 1991); Food Lion, Inc. v. Capital Cities/ABC, Inc., 887 F. Supp. 811, 813 (M.D.N.C. 1995). In considering a Rule 12(b)(6) motion, a plaintiff's well-pleaded allegations are taken as true and the complaint is viewed in the light most favorable to the plaintiff. Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993). However, as the Supreme Court recently instructed, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, No. 05-1126, 2007 WL 1461066, at *8 (U.S. May 21, 2007) (internal quotations and citations omitted).

A.

Mylan asserts that Mr. Sarli's claim for strict liability should be dismissed because North Carolina does not recognize a cause of action for strict liability." When conflict of law issues arise, a federal court sitting in diversity applies the choice of law rules of the state in which it sits. Volvo Constr. Equip. N. Am., Inc. v. CLM Equip. Co., 386 F.3d 581, 599-600 (4th Cir. 2004) (citing Erie R.R. Co. v. Tompkins, 304 U.S. 64, 79 (1938)). Thus, in this case, North Carolina choice of law rules apply.

In tort actions, North Carolina applies the traditional conflict of laws rule of *lex loci*, the law of the situs of the claim, and "[f]or actions sounding in tort, the state where the injury occurred is considered the situs of the claim." Boudreau v. Baughman, 322 N.C. 331, 335, 368 S.E.2d 849, 853-54 (1988) (citation omitted). Therefore, for causes of action sounding in tort, "the law of the state where the plaintiff was injured controls the outcome of the claim." Stetser v. TAP Pharm. Prods., Inc., 165 N.C. App. 1, 598 S.E.2d 570 (2004).

In this case, Mr. Sarli has alleged that "at all material times to this action," he has resided in California. [Doc. # 3, at 2]. Assuming that this allegation is true and taking the facts in the light most favorable to the plaintiff, Mr. Sarli would have sustained injury in California. Under North Carolina choice of law principles, California law would apply.

Mylan does not dispute that California recognizes a cause of action for strict

liability. Rather, Mylan asserts that "North Carolina law must apply" because "[t]here is not a single cognizable allegation in Plaintiff's Complaint that Plaintiff was prescribed, ingested or harmed by Amnesteem in California. Simply put, Plaintiff has failed to allege any facts that would indicate the law of any jurisdiction other then North Carolina would apply." (Doc. # 15, at 3). In light of the plain allegation in the Complaint that Mr. Sarli resided in California "at all material times to this action," it strains credibility to assert, as Mylan does, that there "is not a single cognizable allegation" in the Complaint that Mr. Sarli suffered injury in California.

Assuming, without deciding at this stage in the litigation, that California law regarding strict liability would be applicable, the Mylan Defendants' Motion to Dismiss the strict liability claim is DENIED.

B.

Mylan seeks dismissal of Mr. Sarli's failure to warn claim on the grounds that such claims are preempted by the federal Food Drug and Cosmetic Act ("FDCA") 21 U.S.C. § 301, *et seq*. The Mylan Defendants do not assert that state law claims are expressly preempted by Congress in the FDCA. Rather, in support of their motion, the Mylan Defendants cite Colaicco v. Apotex, 432 F. Supp. 2d 513 (E.D. Pa. 2006) and In re: Bextra and Celebrex Mktg. Sales Practices & Prod. Liab. Lit., MDL 1699, 2006 WL 2374742 (N.D. Ca. Aug. 16, 2006). In both Colaicco and Bextra, the district courts dismissed the plaintiffs' state law claims on

the grounds that they were preempted by the FDA's recent amendment of its regulations regarding prescription drug labeling.

On January 24, 2006, the FDA issued a final rule governing the "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" (the "Final Rule"). 71 Fed. Reg. 3922 (Jan. 24, 2006). In general, the Final Rule adds new labeling requirements that are meant to "make it easier for health care professionals to access, read, and use information in prescription drug labeling." 71 Fed. Reg. at 3922. The Final Rule became effective on June 30, 2006. Id. In addition to establishing new labeling requirements, the Final Rule also discusses comments to the new rule and FDA responses to the comments. See Final Rule part VI at 71 Fed. Reg. at 3929 *et seq*.

Several comments address the preemptive effect of the new labeling rules. See Final Rule, part VI. D. "Comments on Product Liability Implications of the Proposed Rule," 71 Fed. Reg. at 3934. This subsection of the Final Rule discussing comments regarding preemption is often referred to as the "Preemption Preamble." In the Preemption Preamble, the FDA expressed concern that state law products liability actions "threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs" by allowing "lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public-the central role of FDA-sometimes on behalf of a

single individual or group of individuals." Id. at 3935. The FDA concludes that "under existing preemption principles, FDA approval of labeling . . . preempts conflicting or contrary State law." Id. at 3934.

Since the enactment of the Final Rule, some courts have deferred to FDA's position in the Preemption Preamble and have held that state law failure to warn claims are preempted by the FDCA. See Sykes v. Glaxo-SmithKline, 484 F. Supp. 2d 289 (E.D. Pa. 2007); Colaicco, 432 F. Supp. 2d. at 537-38; In re: Bextra, 2006 WL 2374742 at *12.

However, other courts have found state law claims are not preempted. In re Vioxx Prods. Liab. Litig., --- F. Supp. 2d ---, MDL 1657, 2007 WL 1952964, at *9 (E.D. La. July 3, 2007) (explaining that the Final Rule was not entitled to deference because it is was not promulgated pursuant to FDA rulemaking authority); In re Zyprexa Prods. Liab. Litig., --- F. Supp. 2d ---, 2007 WL 1678078, at *39 (E.D.N.Y. June 11, 2007) (denying motion for summary judgment where there was "no actual conflict between plaintiffs' claims and federal law"); Weiss v. Fujisawa Pharm. Co., 464 F. Supp. 2d 666, (E.D. Ky. 2006) (finding that state law claims were not preempted to the extent they were based on failing to provide additional warnings following FDA's approval of drug label); Perry v. Novartis Pharma. Corp., 456 F. Supp. 2d 678 (E.D. Pa. 2006) (denying motion to dismiss on preemption grounds where compliance with both federal and state law was possible).

In this case, Mr. Sarli asserts, among other things, that Amnesteem

"contained warnings insufficient to alert consumers . . . to the dangerous risks and reactions associated with the drug." [Doc. # 3, ¶ 23]. Assuming for purposes of this motion that the FDA's statements regarding preemption are entitled to deference, the FDA identifies six state law claims that it believes would be preempted by FDA regulation of drug labeling. Of the six claims identified by the FDA in the Preemption Preamble, two are potentially applicable in this case.

First, the FDA would find as preempted a state law claim "that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, *the substance of which had been proposed to FDA for inclusion in labeling*, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn." 71 Fed. Reg. at 3934 (emphasis added). Based on the FDA's description of this claim, the FDA would consider a state law failure to warn claim preempted only if the plaintiff sought to impose liability for failure to include warning language that had been proposed to the FDA and rejected by the FDA. This was the fact situation in Colaicco; the FDA had "repeatedly determined that there was inadequate evidence of an association between" use of the drug Paxil and increased risk of suicide and "such a warning statement would actually have been 'false and misleading,' and thus contrary to federal law." Colacicco, 432 F. Supp. 2d at 524 (quoting FDA amicus brief). In such a case, imposing liability for failure to warn would create a direct conflict between state law and federal law because it would be impossible for a drug

manufacturer to comply with both.

In addition, the FDA also concluded in the Final Rule that "claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in the rule" are preempted. Interpreting this language, the Bextra court explained, "the FDA's view is that a claim is preempted if the FDA determined that the warning the plaintiff seeks to impose is not supported by the evidence before the FDA." 2006 WL 2364742, at *9. Thus, if the FDA determined that a warning was not warranted based on the evidence that had been submitted to the FDA, regardless of whether the inclusion of that warning would result in the misbranding of the drug as in the first preemption scenario discussed above, then a claim asserting the impropriety of such failure to include the warning at issue would be preempted.

In the current posture of this case, it cannot be determined that Mr. Sarli's state law claims would conflict with FDA drug labeling regulation such that it would be impossible for the Mylan Defendants to comply with both state law and federal law. There is nothing in the Complaint to suggest that the warnings at issue here had been submitted to the FDA for approval and had been rejected by the FDA. As such, Mr. Sarli's failure to warn claim is not subject to dismissal on the grounds that it is preempted by federal law. See Perry, 456 F. Supp. 2d at 684; Weiss, 464 F. Supp. 2d at 676 (finding no preemption where "the FDA had

not made a conclusive finding regarding a link between" the drug at issue and the medical conditions the plaintiff asserted were caused by the drug). Indeed, the FDA recognized in the Preemption Preamble that its "regulation of prescription drug labeling will not preempt all state law actions" and explained that state law actions should be allowed where the state law requirements "parallel FDA requirements." 71 Fed. Reg. at 3936. The Motion to Dismiss on the basis of preemption is DENIED.

C.

The Mylan Defendants also assert that Mr. Sarli's failure to warn, negligence, and fraud/misrepresentation claims are barred by the applicable statutes of limitations. In the Complaint, which was filed on November 20, 2006, Mr. Sarli asserts that he "was prescribed Amnesteem on August 21, 2003, September 18, 2003, October 21, 2003, and November 2, 2003, and took Amnesteem as prescribed." [Doc. #3, ¶ 16]. The Mylan Defendants assert that these dates fall outside the three-year North Carolina statute of limitation for negligence actions, the two-year California statute of limitation for negligence actions, and the three-year statute of limitations for fraud claims under both North Carolina and California law.[1]

Under North Carolina General Statutes § 1-52(16), a cause of action for

[1]As discussed above, at this stage in the proceedings, it cannot be determined whether California law or North Carolina law, including the North Carolina "borrowing statute," would apply to Mr. Sarli's claims.

personal injury or physical property damage "shall not accrue until bodily harm to the claimant . . . becomes apparent or ought reasonably to have become apparent to the claimant, whichever event first occurs." N.C. Gen. Stat. § 1-52(16). North Carolina also applies the discovery rule to fraud actions. N.C. Gen. Stat. § 1-52(9) ("For relief on the ground of fraud . . . the cause of action shall not be deemed to have accrued until the discovery by the aggrieved party of the facts constituting fraud.").

Similarly, California applies a discovery rule to negligence and fraud actions. Jolly v. Eli Lilly & Co., 44 Cal. 3d 1103, 1109, 751 P.2d 923, 926-27 (1988) ("The discovery rule provides that the accrual date of a cause of action is delayed until the plaintiff is aware of her injury and its negligent cause."); Fox v. Ethicon Endo-Surgery, Inc., 35 Cal. 4th 797, 807, 110 P.3d 914, 920 (2005) (explaining that the delayed discovery rule "delays accrual until the plaintiff has, or should have, inquiry notice of the cause of action").

Thus, under either North Carolina law or California law, the statute of limitations would not begin to run on the date that Mr. Sarli last ingested Amnesteem. Rather, Mr. Sarli's cause of action would accrue only when he became aware of his injuries and the possible cause of those injuries. Currently, the Complaint does not contain any allegations regarding the approximate date on which Mr. Sarli became ill or when he discovered that his injuries could have been caused by his ingestion of Amnesteem. Mr. Sarli has sought leave to amend his

Complaint to add particular facts regarding discovery of the harm he believes was caused by Amnesteem. [Doc. #14 at 16].

Under Rule 15(a) of the Federal Rules of Civil Procedure, leave to amend a pleading "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a). Generally, a party "should be permitted to amend a pleading unless the amendment would prejudice the opposing party, the amending party has acted in bad faith, or the amendment would be futile." In re Cree, Inc. Secs. Litig., 333 F. Supp. 2d 461, 478 (M.D.N.C. 2004) (citing Foman v. Davis, 371 U.S. 178, 182 (1962) and Johnson v. Oroweat Foods Co., 785 F.2d 503, 509 (4th Cir.1986). At this early stage in the litigation, none of these factors would preclude amendment of the Complaint.

Pursuant to Rule 15(a) of the Federal Rules of Civil Procedure, Mr. Sarli may file an Amended Complaint to include allegations regarding when he discovered that his alleged injuries could have been caused by Amnesteem. The Amended Complaint must be filed within 20 days of the date of his Order. The Motion to Dismiss on the basis of the statute of limitations is DENIED.

D.

Finally, the Mylan Defendants have moved to dismiss the Fourth Count in Mr. Sarli's Complaint, which asserts a cause of action for fraud and misrepresentation, for failure to comply with the particularity requirement of Rule 9(b) of the Federal Rules of Civil Procedure. Under Rule 9(b), "in all averments of

fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). The particularity element requires that a plaintiff plead the "time, place, and contents of the alleged fraudulent representation, as well as the identity of each person making the misrepresentation and what was obtained thereby." Liner v. DiCresce, 905 F. Supp. 280, 287 (M.D.N.C.1994). In addition, "where there are multiple defendants, plaintiffs must allege all claims with particularity as to each defendant." Dealers Supply Co., Inc. v. Cheil Indus. Inc., 348 F. Supp. 2d 579, 589 (M.D.N.C. 2004).

The Complaint in this matter contains assertions that (1) "Defendants fraudulently, intentionally and/or negligently misrepresented . . . the safety and effectiveness" of Amnesteem; (2) "Defendants either knew or should have known that the representations were false"; and (3) "Defendants made the representations . . . with the intention and specific desire that the Plaintiff and the consuming public would rely on such in selecting the drug(s) as treatment for acne." [Doc. # 3, ¶¶ 35-38]. These allegations are not asserted with particularity as to each defendant; rather the Complaint makes these allegations as to all of the defendants collectively. Such an allegation is not sufficient under Rule 9(b).

However, as noted above, Rule 15(a) requires that Mr. Sarli should be allowed to amend his Complaint. Accordingly, Mr. Sarli has 20 days from the date of this Order within which to file an Amended Complaint that will comply with Rule 9(b). The Motion to Dismiss for failure to comply with the particularity requirement

of Rule 9(b) is DENIED.

II.

For the reasons set forth above, the Motion to Dismiss [Doc. # 6] is DENIED. Within 20 days of the date of this Order, Mr. Sarli should file an amended Complaint.

This the day of July 19, 2007

/s/ N. Carlton Tilley, Jr.
United States District Judge